REMARKS

Claims 1-32 are pending in this application. Claims 2, 4, 6, 16 and 21-23 have been withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Claims 1, 3, 5, 7-15, 17-20, and 24-32 are presented for the Examiner's review and consideration. Applicants appreciate the Examiner's indication that claims 12-15 contain allowable subject matter.

As an initial matter, applicants acknowledge the Examiner's statement that applicant's proposed title, "Fixation Device and Method for Securing a Graft to Bone" has been approved. Additionally, Applicants restate their position that claims 1, 7-11, 17-20, and 24 are generic to Species A, B, C, and D and that dependent claims 2, 4, 6, and 16 should be allowed upon allowance of the base claim.

Claims 1, 3, 5, 24-32, 25 and 29-30 (Rosenberg)

In the Office Action, claims 1, 3, 5, 24-32, 25 and 29-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,152,790 to Rosenberg et al. ("Rosenberg"). In part, the Examiner stated:

> "Rosenberg et al disclose a ligament reconstruction graft apparatus with an implant body (figure 2, #22) having a first and second end (figure 2, #36 and 34). Rosenberg discloses a first end of the implant body (figure 2, #34) in which an insertion tool[s] [*sic.*] is received through (see figure 3, #60). Further, Rosenberg discloses a second end (figure 2, 34) in which the coupling member is attached to (figure 2, #36).
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> Rosenberg also discloses a graft interface member (figure 2, #20) having a graft holding portion (figure 2, #50) and an implant coupling portion (figure 2, #48). The implant body is able to rotate independently of the graft interface member (column 5, lines 46-49). Further, the graft holding portion has a central longitudinal axis (figure 3, #4) that is adapted to hold a graft aligned with the central longitudinal axis as shown in figure 6.
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> Rosenberg fails to show that the implant coupling portion is adapted to be received in the recess of the implant body. Instead, Rosenberg shows that the implant coupling portion is dimensioned to form a press fit of mating relationship with the trailing end of the implant body.
>
> Therefore, it would have been obvious to provide[d] *sic.* a recess to attach the implant coupling portion with the implant body because a recess, similar to a mating region perform adequate coupling functions."
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> (Office Action, page 2, line 24 to page 3, line 21).

Independent claim 1

Independent claim 1 recites, *inter alia*, a fixation device comprising an implant body having first and second ends, the first end having an opening configured and

adapted to receive an insertion tool and the second end having a recess. Independent claim 1 further requires a graft interface member having a graft holding portion and an implant coupling portion, at least a portion of the coupling portion being configured and adapted to be received in the recess to permit the implant body to rotate independently of the graft interface member.

Rosenberg fails to disclose, teach or suggest a fixation device having an "implant coupling portion" as recited by claim 1.

As acknowledged by the Examiner, the purported graft interface member (20) of Rosenberg is not configured and adapted to be received in the purported recess on the purported second end (34) of the purported implant body (22), as required by claim 1.[1] Moreover, trailing end (36) is the purported first end of the purported implant body. Therefore, modifying the implant of Rosenberg to include "a recess to attach the implant coupling portion with the implant body" on an exterior surface of the trailing end (i.e., the purported first end) would be insufficient to render obvious claim 1, because, claim 1 requires a graft interface member to be received into the recess on the second end of the implant body.

Also, Rosenberg teaches away from modifying anchor assembly 16 so that rotatable ring 20 is received within bore 32. For example, Rosenberg discloses a two-part assembly wherein the ring member is attached to an exterior surface of the trailing end of the implant body.[2] By contrast, the two-part assembly of Rosenberg eliminates insert member 18 of the three-part assembly, which is inserted in bore 32 and affixed to the implant body.[3] In addition, modifying the three part anchor assembly so that the insert member 18 is combined with ring 20 to form a single insert that is affixed to the anchor would prevent the ring from

[1] "Rosenberg, however, fails to show that the implant coupling portion is adapted to be received in the recess of the implant body. Instead, Rosenberg shows that the implant coupling portion is dimensioned to form a press fit or mating relationship with the trailing end of the implant body. (Office Action, page 3, lines 15-18).

[2] "[I]t is also possible within the scope of the invention to provide a two-part assembly. In such a device, the sleeve member would be manufactured with an annular groove and flange at its trailing end and the insert member would be eliminated. The ring member would be snapped onto or formed over the flange so that the annular ridge 48 would fit within and be able to freely rotate in the groove. The technique for implanting such a device would be the same as that described above with respect to the three-part anchor assembly 16." (Rosenberg; 5:41-51).

[3] Anchor assembly 16 has an insert member 18, a rotatable ring 20 and a threaded sleeve member 22. (Id., 3:25-26). The insert member 18 has a cylindrical body 38 and a flanged head 40 at one end. (Id., 3:50-51). The flanged head 40 is formed to extend beyond the length of the sleeve member 22 forming an annular groove 46 situated between the head 40 and the trailing end 36 of the sleeve member 22. (Id., 4:2-5). When the anchor assembly is assembled, the ring member 20 is first assembled on the insert member 18, and then the insert member is inserted into the sleeve member 22 and welded in place. (Id., 4:12-15). (Emphasis added).

rotating independently of the anchor.[4] Thus, Rosenberg fails to disclose, teach or suggest a fixation device having an "implant coupling portion" as recited by claim 1.

Independent claim 1 further requires a graft interface member having a graft holding portion wherein the graft holding portion has a central longitudinal axis and is configured and adapted to hold a graft aligned with the central longitudinal axis.

The Examiner stated:

> "Rosenberg also fails to show that the first end of the graft is attached to the graft interface portion along the central longitudinal axis. The graphs are attached to wall of the implant coupling portion, however, the graph is aligned at its central longitudinal axis when inserted into the body (see figures 5 and 6). Therefore it would have been obvious to have provided the graft at the implant body's central axis since both devices attach the graft along the central longitudinal axis once in the body.
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> (Office Action, page 3 line 22 to page 4 line 7).

Rosenberg also fails to disclose, teach or suggest a fixation device having a "graft holding portion" as recited by claim 1. In fact, Rosenberg teaches away from modifying the anchor assembly 16 to provide the "graft at the implant body's central axis" as stated by the Examiner. Rosenberg teaches that the anchor has a tool receiving central opening. (Rosenberg, 2:21-25). The tool receiving opening preferably extends through the entire length of the anchor so that it cab be manipulatable by a driver from either end. (Rosenberg 2:32-35). The driver instrument 60 is inserted into the central opening 44 in the anchor. (Rosenberg 4:38-39). In this regard, Rosenberg teaches that care should be taken not to damage the tendon grafts 24 and 24' (*Id.*, 4:39-41). The grafts are positioned and held firmly around shaft 64 of the driver and the anchor-graft-driver assembly is inserted into the joint through the tibial tunnel. (*Id.*, 4:39-41). Providing the "graft at the implant body's central axis" where the implant of Rosenberg is designed to receive the driver would block the access of the driving tool and increase the likelihood of damaging the grafts during insertion into the joint as the result of interference from the driver. Thus, Rosenberg also fails to disclose, teach or suggest a fixation device having a "graft holding portion" as recited by claim 1.

For these reasons applicants respectfully submit that Rosenberg is insufficient to render obvious the fixation device of independent claim 1.

[4] The anchor is turned by the driver instrument into the femoral tunnel while the tendon graft or prosthesis ligament is secured to a loose ring and thus does not turn or rotate with the anchor. (Id., 2:52-56).

Dependent claims 3, 5 and 25-28

With respect to claims 3, 5, and 25-28 which depend from independent claim 1, applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features and elements of independent claim 1, these claims are also patentably distinct from Rosenberg for the same reasons as claim 1, as well as the additional features of the respective claims.

Independent claims 24 and 29

With respect to independent method claims 24 and 29, the Examiner stated (as previously described with respect to claim 1) that "Rosenberg also fails to show that the first end of the graft is attached to the graft interface portion along the central longitudinal axis," but that "it would have been obvious to have provided the graft at the implant body's central axis since both devices attach the graft along the central longitudinal axis once in the body." Therefore, the Examiner stated, "the methods as recited it would have been obvious in view of Rosenberg." (Office Action, page 4 lines 6-7). As previously described with respect to claim 1, Rosenberg teaches away from providing a graft at the implant body's central axis. Thus, applicant's respectfully submit that for at least this reason alone, claims 24 and 29 are patentable over Rosenberg.

Moreover, Rosenberg does not disclose teach, or suggest a graft interface portion having first and second surfaces, providing a graft having first and second opposing ends, and trapping the first end of the graft between the first and second surfaces as required by claim 29. Thus, applicants submit that claim 29 is also patentable over Rosenberg for this additional reason.

Dependent claims 30-32

With respect to claims 30-32, which depend from independent claim 29, applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features and elements of independent claim 29, these claims are also patentably distinct from Rosenberg for the same reasons as claim 29, as well as the additional features of the respective claims.

Claims 7-11 (Rosenberg in view of Hitomi)

Clams 7-11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Roseneberg in view U.S. Patent No. 5,643,267 of Hitomi et al. ("Hitomi"). The examiner stated:

> "Rosenberg does not disclose an implant coulping portion with a flexible post, slotted flared tip portion or a under cut section in the second opening of the implant body. Further Rosenberg fails to disclose an implant body with internal thread portion. . . it would have been obvious to one of ordinary skill in the art to modify the snap fixation device of Rosen berg with the snap connection mean in Hitomi in order to provide a more secure means to connect the implant body and the graft interface member."
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> (Office Action, page 3 line 22 to page 4 line 7).

Claims 7-11 depend from independent claim 1. As stated above, Rosenberg fails to disclose, teach or suggest all the limitations of independent claim 1. Hitomi discloses a bone connector for joining cut bone ends. Hitomi fails to remedy the deficiencies of Rosenberg (e.g., Hitomi does not disclose, teach, or suggest "a graft interface member," as recited in claim 1.) Applicants, therefore, submit that Rosenberg and Hitomi, either alone or in combination, do not disclose, teach or suggest the limitations of claim 1. With respect to claims 7-11, applicants submit that, because these claims define more particular aspects of applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over Rosenberg and Hitomi, either alone or in combination for the above reasons, as well as the particular additional limitations expressed in each of those claims.

Dependent claims 18 and 19 (Rosenberg in view of Chauvin)

Claims 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Roseneberg in view of U.S. Patent No. 6,129,763 to Chauvin et al. ("Chauvin"). The examiner stated:

> "Rosenberg does not disclose an internally threaded implant body. . . Chauvin discloses an expandable osteosythesis cage, which includes an internally threaded implant body. Coupling the graft member with the implant body thorough the use on internal threads provides an efficient means to connect and disconnect the two devices as would have been obvious to one of ordinary skill in the art."
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> (Office Action, page 5 lines 8-18)

Claims 18 and 19 depend from independent claim 1. As previously described, Rosenberg fails to disclose, teach or suggest all the limitations of independent claim 1. Chauvin discloses an implant designed to be slid between the facing faces of two consecutive vertebrae in order to maintain a given distance between them by fixing the two vertebrae together. (Chauvin; 1:8-14). Chauvin fails to remedy the deficiencies of Rosenberg (e.g., Chauvin does not disclose, teach, or suggest "a graft interface member," as recited in claim 1). With respect to

claims 18 and 19, applicants submit that, because these claims define more particular aspects of applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over Rosenberg and Chauvin, either alone or in combination for the above reasons, as well as the particular additional limitations expressed in each of those claims.

Dependent claims 26-28 (Rosenberg in view of Suddaby

Claims 26-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of U.S. Patent No. 6,159,244 to Suddaby ("Suddaby"). The examiner stated:

> "Rosenberg fails to disclose a graft holding portion having two seprate members which are configured to mate or snap together. . . .Suddaby discloses an expandable implant, which has a cage comprising of two parts (10# and #12). The two parts connect or are snapped together with each other (see figure 2). . . .Therefore, in view of Suddaby, it would have been obvious to have modified the singular cage portion of Rosenberg with the two members cage portion of Suddaby in order to gain versatility when faced with complex variability during surgery."
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> (Office Action, page 5 line 22 to page 6, line 10).

Claims 26-28 depend from claim 1. As described above, Rosenberg does not disclose, teach or suggest all the limitations recited by claim 1. Suddaby, which is directed toward an intervertebral fusion implant, does not remedy the deficiencies of Rosenberg (e.g., Suddaby does not disclose, teach, or suggest "a graft interface member," as recited in claim 1). Applicants, therefore, submit that Rosenberg and Suddaby, either alone or in combination, do not disclose, teach or suggest the limitations of claim 1. With respect to claims 26-28, applicants submit that, because these claims define more particular aspects of applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over Rosenberg and Suddaby, either alone or in combination for the above reasons, as well as the particular additional limitations expressed in each of those claims.

In view of the foregoing amendments and remarks, it is submitted that all rejections have been overcome and should be withdrawn, and thus all claims are in condition for allowance. Reconsideration of the application in view of the foregoing amendments and remarks is respectfully requested.

Applicant believes that fees are due in connection with the submission of this amendment as calculated on the attached Petition for Extension of Time.

Should any other fees be required, please charge all required fees under 37 C.F.R. 1.17 to Pennie & Edmonds Deposit Account No. 16-1150.

Respectfully submitted,

Date September 22, 2003

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Enclosures